K100881
page 1/2

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510(k) Summary

Date Prepared: January 20, 2010

Submitter's Information

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APR 1 4 2010

Device Name and Classification:

Product Name:	Synapse Obliquus MIP/MPR/Fusion software
Classification Name:	Picture Archiving Communication System (PACS)
Classification Panel:	Radiology
CFR Section:	21 CFR 892.2050
Device Class:	Class II
Product Code:	LLZ

Substantial Equivalence/Predicate Devices:

Synapse 3D (MIP/MPR) Image Visualization Software OBLIQUUS - K061672
GE Advantage Windows CT/PET Fusion - K010336

Synapse Obliquus MIP/MPR/Fusion Software and the predicate Synapse 3D (MIP/MPR) Image Visualization software OBLIQUUS (K061672) perform the same functions except PET displaying feature and Fusion feature. However these two features are equivalent to the GE Advantage Windows CT/PET Fusion (K010336) as shown in the comparison table in Section 12. The Synapse Obliquus MIP/MPR/Fusion Software and the two predicate devices are all software devices for displaying and/or comparing 3D studies. The Synapse Obliquus MIP/MPR/Fusion Software intended use is essentially a combination of the two predicate device intended uses. Thus the Synapse Obliquus MIP/MPR/Fusion Software is substantially equivalent to the combination of the two predicates.

Description of the Device:

Synapse Obliquus MIP/MPR/Fusion Software (this submission) is an upgraded version of the Synapse 3D Visualization Software Obliquus (K061672) with all previous features plus a newly developed Fusion feature. The major change is the addition of Fusion. Fusion blends images from CT and PET series and displays the blended series using various color tables assigned to one of the two source series. A few improvements have also been made to the functionality cleared in K061672. It will now be possible to add annotations in the MPR viewer and length measurement and ROI measurement functions have been added to Common Image Processing Features (for all Viewers).

Intended Use:

Synapse Obliquus MIP/MPR/Fusion software enables the display of 3D (MIP/MPR) visualization of CT, MR, and PET studies and fusion or blending of CT and PET studies. Typical users are radiologists, technologists and clinicians. Obliquus is not intended for Mammography use.

Safety Information:

Synapse Obliquus MIP/MPR/Fusion Software introduces no new safety or efficacy issues other than those already identified with the predicate devices. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Conclusion:

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject device to be as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

FujiFilm Medical Systems, USA Inc.
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

APR 1 4 2010

Re: K100881
Trade/Device Name: Synapse Obliquus MIP/MPR/Fusion Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 25, 2010
Received: March 30, 2010

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **k100881**

Device Name: Synapse Obliquus MIP/MPR/Fusion Software

Indications for Use:

"Synapse Obliquus MIP/MPS/Fusion software enables the display of 3D (MIP/MPR) visualization of CT, MR and PET studies and fusion or blending of CT and PET studies. Typical users are radiologists, technologists, and clinicians.

Obliquus is not intended for mammography use."

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Robert A Becker Jr

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K100881